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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

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b. Identifiers/Open-Ended Terms

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Washington, DC 20460

EPA

Pesticide Fact Sheet

Name of Chemical: Dodine
Reason for Issuance: Registration Standard
Date Issued: February 1987
Fact Sheet Number: 135

1. Description of the Chemicals

Chemical Name:	Dodecylguanidine acetate	Dodecylguanidine hydrochloride (DGH)	Dodecylguanidine terephthalate (DGT)
Common Name:	Dodine		
Brand Names:	Doguadine, Tsitrex, Dodine acetate, CL 7521, Dodecylguanidine monoacetate, AC 5223, Cyprex, Melprex, Carpene, Curitan, Syllit, Venturol, and Vondodine	Cytox 2013	Durotex 7487-A
CAS Registry Number:	2439-10-3	13590-97-1	19727-17-4
EPA/OPP Pesticide Chemical Code:	044301	044303	044302
Empirical Formula:	$C_{15}H_{33}N_3O_2$	$C_{13}H_{30}N_3Cl$	Not Available
Pesticide Type:	Fungicide and industrial biocide/ preservative	Industrial biocide/ preservative	Industrial preservative
Major U.S. Producers:	American Cyanamid, Onyx Chemical, Aceto Chemical	Betz	Ventron Chemical

First registered: 1956

2. Use Patterns and Formulations

	Dodecylguanidine acetate	Dodecylguanidine hydrochloride (DGH)	Dodecylguanidine terephthalate (DGT)
Registered Sites:	Fruit and nut trees, ornamentals, industrial aquatic sites, pulp and paper products	Industrial aquatic sites	Industrial preservative
Predominant Use(s):	Apple trees	Industrial biocide/ preservative	Non-clothing textiles
Formulation Types Registered:	Wettable powder/ dust, soluble concentrate/ liquid	Soluble concentrate/ liquid	Soluble concentrate/ liquid
Method(s) of Application:	Foliar spray, Air blast spray, Dusting equipment drawn by tractor or truck, Boom sprayer, Aerial spray, Automatic pump, Drip Feed, Pour	Automatic pump, Drip Feed, pour	Manual pour, Conventional padding equipment

3. Science Findings

Summary: EPA has only limited data pertaining to dodecylguanidine acetate (dodine), dodecylguanidine hydrochloride (DGH), and dodecylguanidine terephthalate (DGT). The available data describing DGH and DGT are limited to some product identity and disclosure of ingredients. There are no data available describing environmental fate, ecological effects, or toxicology for DGH and DGT.

Chemical Characteristics (dodine, DGH, and DGT):

	Dodine	DGH	DGT
Color:	White	Not Available	Not Available
Physical State:	Crystals, Slightly waxy	Not Available	Not Available
Melting Point:	136C	Not Available	Not Available
Solubility:	Soluble at 7-23% in low molecular weight alcohols at room temperture. Soluble in acids and 0.06% soluble in water at 25C. Insoluble in most other solvents. Soluble in ethanol.	Not Available	Not Available
Molecular Weight:	287.4	263.9	Not Available

Environmental Fate (dodine): There are no available data allowing EPA to assess the environmental fate of dodine.

Ecological Effects (dodine): EPA does not have data describing toxicity of technical grade dodine to birds or aquatic organisms. However, data on a multiple active ingredient formulation containing 95% dodine indicate that dodine is slightly toxic to birds and highly toxic to freshwater fish. A laboratory acute contact study indicates that dodine is relatively nontoxic to honey bees.

Although the absence of data on technical dodine limits conclusions, available data suggest that there would be no immediate hazard to avian species from terrestial food crop residues. Data show that the acute LD_{50} for avian species for a formulated product are in the range of 700 to 2000 ppm. Estimation of residues to which birds will be exposed are approximately 70 - 170 ppm on leaves and 3-7 ppm on fruit. The estimated environmental concentration (EEC) in aquatic systems, 15 ppb, is well below the toxic level to fish (650 - 870 ppb). Based on the incomplete data base, terrestrial dodine food residues pose no apparent acute hazards to any avian or aquatic species that are Federally designated threatened or endangered.

Toxicology (dodine): The available data allow EPA to adequately characterize the acute effects of dodine. The findings of acute oral LD_{50} of 1.46 g/kg, a one hour LC_{50} of 1.05-1.79 mg/l, and no deaths in test animals after acute dermal exposure to 2 g/kg indicate moderate lethal potency (Category III). Severe irritation in both washed and unwashed eyes and severe dermal irritation including erythema and edema were seen in rabbits (Category I). Based on a 21-day skin sensitization study, there is no evidence of sensitization in humans.

Although many of the available studies of dodine do not satisfy EPA's data requirements, various effects of dodine can be identified based on existing studies. Subchronic dietary exposure of dogs caused changes in thyroid cells indicative of stimulation (No Observed Effects Level (NOEL) = 1.25 mg/kg). In another study, chronic dietary exposure in the rat caused reduced weight gain in both sexes, accompanied by a comparable reduction in food consumption in males (NOEL = 10 mg/kg). EPA classifies this rat study as supplementary because the histopathology analysis was inadequate. In a reproductive study, dietary exposure of parent mice caused decreases in the number of pups per litter surviving until day 5 and weaning (Lowest Observed Effect Level (LOEL) = 74-89 mg/kg. The results of an Ames assay for mutagenicity of 5 strains of bacteria with and without metabolic activation were negative.

Tolerance Reassessment (dodine): The initial Acceptable Daily Intake (ADI) and Provisional ADI (PADI) for dodine are both based on a chronic 12 month dog study. Treated dogs exhibited histological changes in the thyroid described as increased vascularity and changes in the shape of follicular epithelial cells from squamous to cuboidal. These changes are considered to be indicative of thyroid stimulation. The No Observed Effect Level (NOEL) of 50 ppm (1.25 mg/kg) reported in the study was confirmed in the reassessment for this standard.

EPA calculated a PADI of 0.0013 mg/kg for dodine. This value is based on a safety factor of 1000 for interspecific and intraspecific extrapolations and the uncertainty of risk due to gaps in the chronic data base. The PADI is equivalent to a Maximum Permissible Intake (MPI) of 0.078 mg/day. The Theoretical Maximum Residue Concentration (TMRC) of dodine in the daily diet is 0.005117 mg/kg/day (0.307 mg/day for a 60 kg person). Under these assumptions, 393.6% of the PADI is used.

4. Summary of Regulatory Positions and Rationales

— EPA will not, at this time place dodine, DGH, or DGT into Special Review because, based on available data, none of these chemicals meets or exceeds the criteria for conducting a Special Review (40 CFR Part 154.7).

— EPA will not require restricted use classification for end-use products containing dodine, DGH, or DGT. Dodine is not acutely toxic via the inhalation or oral routes. There are data demonstrating that exposure to dodine can cause severe ocular and dermal irritation. However, labeling provisions for protective clothing will minimize acute risks from use of products containing dodine.

— EPA will not require specific label statements pertaining to the protection of Federally designated threatened or endangered species because the available data for dodine do not suggest that terrestrial food residues pose acute hazards to threatened or endangered species.

— EPA is not proposing a label advisory statement regarding groundwater because there are, at present, no data suggesting cause for groundwater concerns.

— EPA is adopting the following positions regarding dodine residues and tolerances: (1) EPA will revoke, within one year of issuance of this standard, the spinach tolerance if no use for this crop is proposed. (2) EPA will revoke or replace the zero tolerances for meat and milk. (3) EPA will delete the restriction against feeding apple pomace to livestock after registrants submit data demonstrating either no residues in pomace or the need for a tolerance.

— EPA is not imposing a reentry internal for dodine at this time. However, EPA is requiring data needed to establish a reentry interval.

— Labels of products containing dodine must bear language requiring the use of either protective clothing or closed mixing - loading systems to reduce the potential risk of skin and eye exposure.

— EPA will not allow any significant new uses of dodine, DGH, or DGT until data gaps identified in this Standard are filled because the available data are insufficient for EPA to evaluate risks associated with the uses of these chemcials.

— EPA will review immediately upon receipt of the data:

40 CFR Part 158.125 Residue chemistry

171-4 Nature of metabolism in plants - dodine

40 CFR Part 158.135 Toxicology

82-1 90-day feeding - DGT
82-2 21-day dermal - dodine
83-1 Chronic toxicity, rodent and non-rodent - dodine
83-2 Oncogenicity, 2 species - dodine
83-3 Teratogenicity, 2 species - dodine
83-4 Reproduction, 2 generation - dodine

40 CFR Part 158.145 Ecological effects

72-3 Oyster LC_{50} - dodine, DGH, and DGT
72-7 Aquatic residue monitoring - dodine, DGH, and DGT

5. Summary of Major Data Gaps

Study	Due Date Dodine	DGH	DGT
Product Chemistry			
Product identity and composition	Jan. 1988	Nov. 1987	Nov. 1987
Analysis and certification of product ingredients	July 1988	May 1988	May 1988
Physical and chemical characteristics	Jan. 1987	Nov. 1987	Nov. 1987
Residue Chemistry (only dodine)			
Metabolism	July 1989		
Analytical methods	Jan. 1989		
Storage stability	July 1989		
Residue in plants	July 1988 July 1989		
Residue in animal products	Jan. 1989		
Environmental Fate (dodine and DGH)			
Degradation (laboratory)	Apr. 1988	Feb. 1988	-
Photogradation	Apr. 1988	Feb. 1988	-
Metabolism (laboratory)	Oct. 1989	Aug. 1989	-
Mobility	July 1988		
Dissipation (field)	Oct. 1989 - Sept 1991	Aug. 1989	-
Accumulation	July 1988 - Sept 1990	May 1988 - July 1990	- -
Toxicology			
Acute studies	-	Apr. 1988	Feb. 1989
90 day feeding (rodent)	-	-	Sept 1988
90 day feeding (non-rodent)	-	Jan. 1989	Reserved
21 day dermal	July 1988	May 1988	Reserved
90 day dermal	-	-	Reserved
90 day inhalation	-	-	Reserved
Chronic toxicity (rodent & non-rodent)	Sept 1991	-	Reserved
Oral oncogenicity (rat and mouse)	Sept 1991	-	Reserved
Teratogenicity (2 species)	Oct. 1988	-	Reserved
Reproduction	Jan. 1990	-	Reserved
Mutagenicity	July 1988	May 1988	Reserved
General metabolism	July 1989	May 1989	Reserved
Wildlife and Aquatic Organisms			
Avian and mammalian studies	Apr. 1988 - July 1989	Feb. 1988	Feb. 1988
Aquatic organisms	Apr. 1988	Feb. 1988	Feb. 1988
Estuarine and marine organism	July 1988	May 1988	May 1988
Aquatic monitoring	July 1989	May 1989	May 1989

Study	Due Date		
	Dodine	DGH	DGT
Reentry			
Foliar dissipation	Sept 1989	-	-
Dermal exposure	Sept 1989	-	-

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